REMARKS

Prior to entry of the present amendment, claims 1-28 are pending. Claims 2, 4, 6, 10-15, and 20-23, due to a Restriction Requirement, are withdrawn from consideration. Claims 1, 16-19, and 24-26 are rejected under 35 U.S.C. § 102, and claims 1, 3, 5, 7-9, 16-19, and 24-28 are rejected under 35 U.S.C. § 103. Applicants address each basis for rejection as follows.

Claim amendments

Claims 1, 2, 4, and 10-25 have been canceled.

Claim 3 has re-written in independent form, and, therefore finds support in original claim 1. The term "direct control" is used in two expressing steps in claim 3 as amended to clarify that a CA promoter (cytomegalovirus enhancer and chicken β-actin promoter) is connected to those genes. Support for this amendment is found, for example, at page 2, lines 27-36, of the English language specification.

In view of the cancellation of claim 1, claims 8 and 9 have been amended to depend from claim 3.

Claim 26 has been amended to reflect the limitations of claim 3, as amended. Support for these amendments is found, for example, at page 24, line 29, to page 25, line 6, and page 27, lines 12-22, of the English language specification.

New claims 29-35 have been added. Support for claims 29-35 is found, for example, at page 14, line 18, to page 15, line 21, of the English language specification. In particular, claims 29-35 are supported by items 1-2, 1-7, 1-3, 1-6, 1-8, and 2-2, respectively.

No new matter has been added by the present amendments. Applicants reserve the right to pursue any cancelled subject matter in this or in a continuing application.

Rejections under 35 U.S.C. § 102

Claim 1 is rejected under 35 U.S.C. § 102(b) as being anticipated by Waning et al. (J. Virol. 76:9284-9297, 2002; "Waning"). Claim 1 has been cancelled. This basis for rejection is moot.

Claims 16-19 and 24-26 are rejected under 35 U.S.C. § 102(b) as anticipated by, or in the alternative, under 35 U.S.C. § 103(a), as obvious over Ito et al. (Microbiol. Immunol. 47:613-617, 2003; "Ito 2003") as evidenced by Ito et al. (J. Virol. 75:9121-9128, 2001; "Ito 2001"). In particular, the Office states (page 4):

> Ito et al teaches a plasmid (pC-T7pol) encoding the T7 RNA polymerase under control of the strong chicken β-actin promoter, see page 614, first column, first full ¶.

As an initial matter, Applicants submit that Ito 2003 only teaches a plasmid encoding the T7 RNA polymerase under control of a "chicken β-actin promoter", and does not teach the "cytomegalovirus enhancer and chicken β-actin promoter-comprising promoter" as is required by the present claims. As Ito 2003 does not describe each and every element of the claimed invention, Ito 2003 cannot anticipate claims 16-19 and 24-26. Nonetheless, the rejection of claim 16-19, 24, and 25 as being anticipated by Ito 2003 is moot because these claims have been cancelled.

Claim 26 has been re-written in independent form, and item (iii) has been added. Claim 26, as amended, requires the mammalian cell to maintain "DNAs encoding minus-strand RNA viral proteins that form a ribonucleoprotein with the genome RNA, wherein the DNAs are operably linked to a promoter comprising a cytomegalovirus enhancer and a chicken β-actin promoter." This feature is neither taught nor suggested by Ito 2003. The anticipation/obviousness rejection of claim 26 as amended over Ito 2003 may be withdrawn.

Rejection under 35 U.S.C. § 103

Claims 1, 3, 5, 7-9, 16-19, and 24-28 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Inoue et al. (J. Virol. 77:6419-6429, 2003; "Inoue") in view of Waning, Ito 2003, Li et al. (J. Virol. 74:6564-6569, 2000; "Li"), and Lerch et al. (International Conference on Negative Strand Viruses 154: Abstract 206, 2003; "Lerch"). The Office states (pages 6 and 7):

> The claimed methods are essentially disclosed by Inoue et al with the exception of the use of a CA [cytomegalovirus enhancer and a chicken β-actin promoter] promoter to express the RNP [ribonucleoprotein] proteins, and the expression of the T7 RNA polymerase from a CA promoter (Inoue et al provide this via a vaccinia virus). The ordinary skilled artisan, seeking a method to prepare SeV [Sendai virus] vectors for gene transfer, would have been motivated to use the CA promoter of Ito or Waning et al to express the SeV RNP proteins of Inoue et al because both Ito and Waning et al teach it to be a superior promoter for expression of such proteins in mammalian cells.
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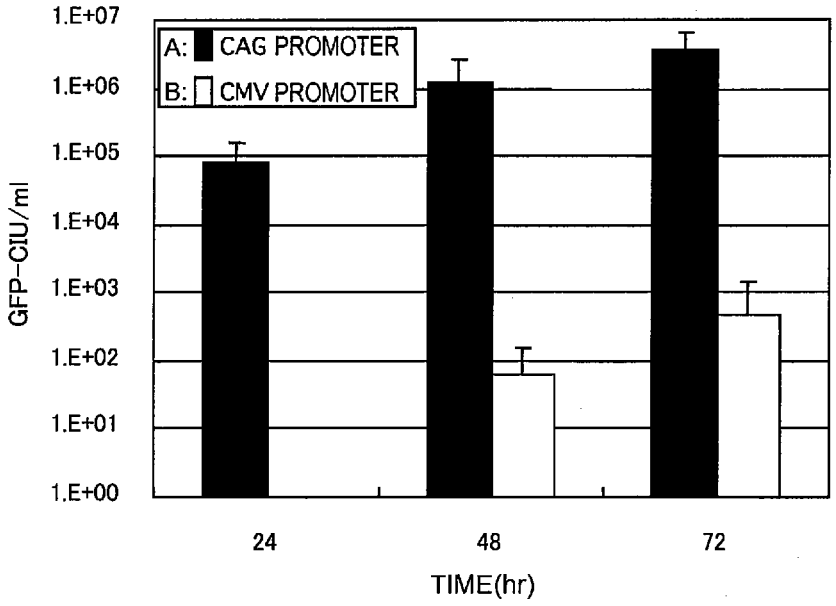
> * * *
>
> It would have been obvious for the skilled artisan to do this because of the known benefit of generating SeV vectors for gene transfer as taught by Inoue et al, and the ease of using an entirely plasmid based system, as taught by Lerch et al.

Applicants submit that the cited art, even if combined, fails to teach or suggest the use of a "cytomegalovirus enhancer and chicken β-actin promoter-comprising promoter" (a CA promoter) as defined in amended claim 3. As the combination of cited art fails to teach or suggest each and every element of the presently claimed invention, it cannot render the claims, as amended, obvious. On this basis alone, the obviousness rejection over the present combination of art should be withdrawn.

Moreover, Applicants submit that the technical solution defined in the pending claims encompasses an unexpected result. Example 9 of the specification shows the comparison of the viral reconstitution efficiency of a CA promoter and a CMV promoter. Expression of an RNA polymerase (for transcribing a viral genome RNA) and viral

proteins was induced by a CA promoter ("CAG PROMOTER" in Fig. 22) or a CMV promoter ("CMV PROMOTER" in Fig. 22). As a result, *"[t]he CA promoter was 1000 times or more efficient for vector reconstitution"* (see page 49, lines 16-17 of the English language specification). In Figure 22, as filed, visually comparing results of a CA promoter and a CMV promoter is difficult because the viral production using a CMV promoter was too low to appear on the scale of the figure. The figure shown below shows the results of the same experiment using a logarithmic scale.



As is evident from the above figure, the method using a CA promoter resulted in 1,000- to 10,000-fold higher viral production compared with the method using a CMV promoter.

Applicants submit that the choice of promoter brought an unexpected and surprising change in viral production (see M.P.E.P. § 716.02(a)). The combination found by the present inventors yielded high titers that were "more than the predictable use of prior art elements according to their established functions" (M.P.E.P. § 2141(I)). The claims as amended require the three elements (a bacteriophage RNA polymerase controlled by CA promoter, minus-strand RNA virus genome RNA controlled by the bacteriophage RNA polymerase, and minus-strand RNA viral proteins controlled by CA

promoter) which yielded the surprising result described in the specification. For this reason as well, Applicants submit that the claims as amended are free of the obviousness rejection over the combination of cited art. This basis for rejection may be withdrawn.

CONCLUSION

Applicants submit that the application is now in condition for allowance, and such action is hereby respectfully requested.

Enclosed is a petition to extend the time period for replying to the Office Action for two (2) months until November 1, 2011.

Authorization is hereby provided to charge the extension fee required by 37 C.F.R. § 1.17(a), as well as any other fees or to apply any credits, to Deposit Account No. 03-2095.

Respectfully submitted,

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